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Appeal Brief
S. Bryce
8/12/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Re. Appellant:	Carl A. Caspers
Serial No.:	09/829,306
Filed:	April 9, 2001
For:	OSMOTIC MEMBRANE AND VACUUM SYSTEM FOR ARTIFICIAL LIMB
Examiner:	William H. Matthews
Group:	3738
Confirmation No.:	6882
Attorney:	Gerald E. Helget
Attorney Docket No.:	33062.37
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Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICANT'S APPEAL BRIEF

Applicant, by his attorney, submits three copies of this Appeal Brief, pursuant to the Office Action mailed May 16, 2003 and 37 C.F.R. § 1.192 in further of the Appeal, the notice of which was filed with the United States Patent and Trademark Office on May 27, 2003.

CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service as First Class Mail, in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

By _____
Date 25 July 03

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I. REAL PARTY IN INTEREST

The real party in interest is Otto Bock HealthCare LP.

II. RELATED APPEALS AND INTERFERENCES

Applicant is unaware of any related appeals or interferences.

III. STATUS OF CLAIMS

The claims on appeal are claims 1 and 4-6.

IV. STATUS OF AMENDMENTS

Amendments made in the paper filed May 7, 2003 have been entered.

V. SUMMARY OF THE INVENTION

The present invention is an apparatus for wicking away perspiration from a residual limb (14, page 7) encased in a liner (92, page 7), the residual limb and liner being inserted into an artificial limb socket (60, page 7) having a first space (62, page 7) between the liner and the socket, the apparatus comprising an osmotic membrane (100, page 7) to encase the residual limb and adapted for placement between the residual limb and the liner, thereby creating a second space (132, page 7) between the residual limb and the liner, the membrane being adapted to allow the passage of water vapor in one direction only, from the residual limb towards the liner, and further comprising a vacuum source (70, page 6) connected to the second space and to the first space, allowing water vapor to pass more readily through the osmotic membrane and wherein application of the vacuum between the liner and the socket draws the residual limb and liner into total contact with the socket interior (62, page 6); a seal means (84, page 7) for sealing the first space and the second space; and a means (80, page 9) to maintain a vacuum in the first space and the second space in the presence of some air leakage past the seal means.

VI. ISSUES

1.) Whether or not claims 1 and 4-6 are non-obvious under 35 U.S.C. § 103(a) over Caspers '709 in view of Norvell?

VII. GROUPING OF CLAIMS

The rejected claims stand or fall together.

VIII. ARGUMENT

A. Claims 1 and 4-6 are not unpatentable under 35 USC 103(a) as being obvious over Caspers '709 in view of Norvell.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.[1] If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness.[2]

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.[3]

Applicant respectfully traverses the § 103 rejection because the office action has not established a *prima facie* case of obviousness.

First, Caspers '709 does not teach a vacuum source connected to a space between the liner and residual limb to lower the partial water vapor pressure in the space.

Careful examination of the Figures in conjunction with the Specification of Caspers '709 will show that vacuum is applied to the space 62 between the liner 92 and the socket, but not between the liner 92 and the limb 14. The Specification teaches, at col. 6 lines 41-49:

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[1] MPEP Sec. 2142

[2] Id.

[3] Id. (emphasis supplied)

> The hypobarically-controlled artificial limb 50 may also include a nonfoamed, nonporous polyurethane liner 92 receiving the residual limb 14 and disposed between the sheath 90 and the residual limb 14. **The liner 92 provides a total-contact hypobaric suction, equal weight distribution socket liner. The liner 92 readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14.**

Thus, it is impossible in Caspers '709 for vacuum applied to the space 62 to also apply between the limb 14 and liner 92, because the liner 92 tacks up to the limb 14 and would not allow vacuum between it and the limb 14.

Applicant respectfully submits that, contrary to the Advisory Action mailed May 16, 2003, Caspers '709 does not teach this limitation.

Norvell also does not teach this limitation.

In addition, Norvell teaches away from the use of a separate osmotic membrane between a liner and the limb, at Col. 2 lines 41-44:

> For example, when inserted into a tight fitting silicone sleeve regularly worn between the wearer and the prosthesis, the bunching of the PTFE material around the side of the limb can lead to chafing and maceration.

This statement would have led one of ordinary skill in the art away from the claimed construction of a separate osmotic membrane between the liner and the limb.

The Examiner is also taking Official Notice that:

> Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the artificial limb disclosed by Caspers '709 by substituting the liner 92 with the osmotic membrane liner taught by Norvell '169 in order to wick perspiration away from the limb providing extra comfort to the wearer.

This is impermissible. As noted above, the prior art "must teach or suggest all the claim limitations." The Examiner has not shown where the prior art teaches or suggests this modification. In fact, the prior art teaches away from making the combination, as discussed above.

Furthermore, the Examiner has not considered evidence in the Specification supporting the patentability of this claim.[4] MPEP states:

> If the examiner determines there is factual support for rejecting the clamed invention under 35 USC 103, the examiner must then consider evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of the evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. The legal standard of "a preponderance of the evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 USC 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

Caspers '709 does not teach the limitation of "a means to maintain a vacuum in the first space and the second space, in the presence of some air leakage past the seal means."

At page 4 of the Specification, Applicant states:

> U.S. Patent No. 5,549,709 discloses several embodiments of a hypobarically-controlled artificial limb. However, all of these embodiments required two sockets: an outer socket and an inner socket. Applicant has found that the present invention offers improved performance without the requirement for two sockets. A single socket works equally well or better than two sockets. **Also, this patent does not disclose a mechanism for maintaining vacuum in the presence of air leakage into the socket.**

Applicant pointed this out to the Examiner in the Amendment and Response filed January 22, 2003 at page 6. The Examiner has not properly considered or weighed Applicant's evidence against the rejection. There is no discussion in the Final Office Action of how the Examiner's statements satisfy the burden of showing a preponderance of the evidence.

Finally, the Examiner has not applied the test of *Graham v. John Deere Co.*[5] The MPEP requires the Examiner to do so.[6] However, the Examiner has made no finding of the

[4] MPEP § 2142

level of ordinary skill in the art.[7] The Examiner has still not applied this test in the Final Office Action.

In view of the foregoing, Appellant asks the Board to overturn the Examiner's rejections and allow all claims.

IX. APPENDIX

The appealed claims are presented in the attached appendix.

Respectfully submitted,

Dated: 25 July 05

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[5] 383 U.S. 1 (1966)

[6] MPEP § 2141

[7] MPEP § 2141.03

APPENDIX

1. (previously amended) In an artificial limb for amputees who have a residual limb, the residual limb being encased in a liner, the residual limb and liner being inserted into an artificial limb socket having a first space between the liner and the socket, an apparatus for wicking away perspiration from the residual limb, the apparatus comprising: an osmotic membrane to encase the residual limb and adapted for placement between the residual limb and the liner, thereby creating a second space between the residual limb and the liner, the membrane being adapted to allow the passage of water vapor in one direction only, from the residual limb towards the liner, further comprising:

(a) a vacuum source connected to the second space between the liner and the residual limb and to the first space between the liner and the socket, wherein application of the vacuum source to the second space between the liner and the residual limb lowers the partial water vapor pressure in the second space, allowing water vapor to pass more readily through the osmotic membrane, and wherein application of the vacuum between the liner and the socket draws the residual limb and liner into total contact with the socket interior;

(b) a seal means for sealing the first space and the second space; and

(c) a means to maintain a vacuum in the first space and the second space, in the presence of some air leakage past the seal means.

4. (previously amended) The apparatus of claim 1, wherein the seal means further comprises a nonfoamed, nonporous polyurethane suspension sleeve for rolling over and covering the socket and a portion of the residual limb.

5. (previously amended) The apparatus of claim 1, wherein the vacuum source is a vacuum pump and the means to maintain the vacuum in the first space and second space is a regulator, and further comprising a power source for the vacuum pump and the regulator.

6. (previously amended) The apparatus of claim 1, wherein the vacuum source and the means to maintain the vacuum in the first space and second space further comprise a weight-actuated vacuum pump.